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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,062	07/20/2004	Shogo Miki	81844.0027	8649

26021 7590 11/16/2006
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EXAMINER

BOUCHELLE, LAURA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/502,062	Applicant(s) MIKI ET AL.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/20/04, 8/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-7, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu et al (US 6533754) in view of Ishida (US 5879369). Hisamatsu discloses a catheter having a balloon 12, a shaft 13, and a guidewire tracking lumen 11 in the distal portion. The guidewire tracking lumen crosses the interior of the balloon and has a guidewire port 141 located less than 10 mm from the proximal end of the inflated balloon (Col. 6, lines 6-8). See Fig. 2. The shaft comprises a material such as SUS or a super elastic material such as Ni-Ti alloy (Col. 6, lines 43-48). The catheter includes a radiopaque marker 121 disposed on the interior of the balloon (Col. 4, lines 58-59). The balloon can be formed of silicone or polyurethane (Col. 7, line 57- Col. 8, line 8).

3. Claim 1 differs from Hisamatsu in calling for the balloon to have an elongation at break of 300% to 1000% and the shaft to have a bending modulus of at least 1 GPa. Ishida teaches a balloon catheter having a balloon with an elongation at break of about 500% and a bending modulus of 2950 kg/cm² (2.35 GPa) to allow the device to have adequate strength to dilate a

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vessel and still be flexible enough to give satisfactory tracking capability (Col. 16, lines 36-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hisamatsu to have elongation at break of about 500% and a bending modulus of 2950 kg/cm^2 (2.35 GPa) as taught by Ishida so that the device has the desired characteristics.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu in view of Ishida as applied to claim 3 above, and further in view of Cragg (US 5085635). Claim 4 differs from the teachings above in calling for the guidewire port to be closed when no guidewire is present in the lumen. Cragg teaches a catheter having a guidewire port that has a valve that is closed when there is no guidewire in the lumen to prevent discharge of fluid from the guidewire port (Col. 2, lines 9-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hisamatsu in view of Ishida to have a guidewire port that has a valve that is closed when there is no guidewire in the lumen as taught by Cragg to prevent discharge of fluid from the guidewire port.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu in view of Ishida as applied to claim 1 above, and further in view of Imran et al (US 5766203). Claim 8 differs from the teachings above in calling for the outer surface of the catheter to be coated. Imran teaches a catheter coated with a layer of tetrafluoroethylene (Teflon®) to allow the shaft to be inserted into the vasculature with minimum friction (Col. 5, lines 3-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device

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of Hisamatsu in view of Ishida to include a tetrafluoroethylene coating as taught by Imran so that the device can be inserted into a vessel with minimum friction.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

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